

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 142/003/PCT; 03-766)

PATENT

In re Application of: Light et al.)
Serial No.: 09/582,492) Before the Examiner: J. Switzer
Filed: March 6, 2002) Group Art Unit: 1634
For: Detection of Human Papilloma)
Virus in Papanicolaou (Pap) Smears)

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL DECLARATION PURSUANT TO 37 C.F.R. § 1.132

I, Gerard J. Nuovo, hereby declare:

1. I am a Professor of Pathology at the Ohio State University Medical Center. I am also a named co-inventor on the above-described patent application. I have an M.D. from the University of Vermont Medical College and have been engaged in research on gynecologic pathology, focusing on cervical diseases, and infectious disease detection, focusing on HPV and *in situ*-based methodologies, for eighteen years. My *curriculum vitae* is attached hereto as Appendix A.

2. I am a named co-inventor, with Elizabeth S. Light, on United States Patent Application No. 09/582,492 (the '492 Application).

3. This Supplemental Declaration incorporates the Declaration Pursuant to 37 C.F.R. § 1.132 executed on September 18, 2006, which was submitted with respect to the instant application.

4. The experimental results described in Example 1 of the '492 Application led us to reduce the proportions of genomic HPV DNA probes prepared from the genomic sequences of HPV types 16 and 31 relative to the concentrations of the genomic sequences of HPV types 18, 33, 35, and 51, thereby eliminating undesired cross-reactivity with the genomic sequence of HPV types 42, 43, or 44.

5. The '492 Application provides the first teaching in the art that the concentrations of the genomic sequences of HPV types 16 and 31 must be lowered relative to the concentrations of the genomic sequences of HPV types 18, 33, 35, and 51 in order to eliminate undesired cross-reactivity with the genomic sequence of HPV types 42, 43, or 44.

6. A researcher in the field of gynecological pathology who has read the '492 Application would understand that the suitable reagents (*i.e.*, reagents that do not cross-react with the genomic sequence of HPV types 42, 43, or 44) could be prepared by modifying the concentrations of the genomic DNA probes specified in Table 2 of the '492 Application.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed: Gerard J. Nuovo, M.D.
Gerard J. Nuovo
Dated: 11/11/07